

REMARKS

This responds to the Final Office Action mailed on July 23, 2009 and to the Advisory Action mailed on December 9, 2009.

Claims 1, 33-42, and 44-46 are amended, no claims are canceled, and no claims are added; as a result, claims 1, 4-10, 13-31, 33-42, 44-54, and 56-60 are pending in this application.

Interview Summary

Applicant thanks Examiner John Pauls for the courtesy of a telephone interview on December 15, 2009 with Applicant's representative John I. Fischer where aspects of the independent claims were discussed. During the interview, proposed language was discussed and it was indicated that the proposed language may overcome the present rejections.

The Rejection of Claims Under § 112

1. Claims 34 - 42, 44-54 and 56-60 are rejected under 35 U.S.C. 112, second paragraph. Applicant has amended claims 34-43 and 44-46 to clarify the claimed subject matter. In view of these amendments, Applicant respectfully submits that the present claims comply with § 112 and requests notification of the same.

The Rejection of Claims Under § 102

2. Claims 1, 4, 13, 14, 16, 17, 26, 27, 30, 33-36, 44-46, 49, 53 and 54 were rejected under 35 U.S.C. 102(e) using Leven (U.S. Publication No. 2004/0172290).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P § 2131. It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, “[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485

(Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added).

Leven fails to establish every element of claim 1:

Leven appears to refer to health monitoring system **200** including a wearable health monitoring device **100** that is capable of communicating information to a user computer system **210** or other computer systems, such as a doctor's computer system **220** or a third party computer system **230**. Leven at ¶ 0036 and FIG. 2. Leven also refers to a configuration where the wearable health monitoring device can detect an operative wireless connection link to transmit collected health indicator data to a remote system. *Id.* at ¶ 0041.

First, Applicant cannot find in the cited portions of Leven any disclosure of “an interface to an implantable medical device,” as claim 1 recites. Instead, Leven clearly and repeatedly refers to a “wearable health monitoring device **100**.” *See, e.g., Id.* at ¶¶ 0014, 0022-0023, and 0037. For example, Leven states “in operation, a health monitoring device **100** can be strapped to one's chest or worn around the neck.” *Id.* at ¶ 0037.

As further evidence, Leven goes into great detail of features that may only be found on an external wearable device, such as analog/digital input ports **135**, a power source **125** with rechargeable power supply, a visual power source indicator **145**, and a display screen **170**. *Id.* at ¶¶ 0023, 0024, 0035, and 0055. The display screen appears to be a highly functional display screen that can be used to “display diagnostic information regarding the health monitoring device **100** and can also be used to display ... directions from a health care professional.” *Id.* at ¶ 0035. These features may be unnecessary or at least non-trivial additions to an implantable medical device. Leven contains no teaching of how one may incorporate such features into an implantable device. In fact, the term “implantable” does not even appear in Leven.

Thus, Applicant respectfully submits that the plain meaning of the term “wearable” in conjunction with the description in Leven provides clear evidence that Leven did not contemplate an implantable device when considering the scope and use of a “wearable health monitoring device **100**.”

Moreover, being that there is no implantable medical device in Leven, Applicant respectfully submits that it logically follows that Leven does not disclose “the implanted medical

device configured to sense and transmit patient health data to the patient management system and comprising a proximity recognition system,” as claim 1 further recites.

Second, although Applicant contends that Leven fails to disclose an implantable medical device, even if *in argendo*, Leven’s wearable health monitoring device may be construed as including an implantable device, Applicant cannot find in the cited portions of Leven any disclosure of “a recognition module ... configured to ... authorize a person implanted with the implantable medical device access to the information access portal,” as claim 1 presently recites.

The Final Office Action relies on paragraphs 0036, 0041, and 0044 of Leven as purportedly supporting the § 102 rejection of this portion of claim 1. Final Office Action at p. 4.

Paragraph 0036 of Leven refers to “providing access to a medical service provider/health professional **225**, such as a doctor, and third party **235**, such as an insurance agency, friends, relatives, or other authorized party.” Clearly, these parties are not ones that have an IMD in them. To wit, they are not “a person implanted with the implantable medical device,” as claim 1 recites. Paragraph 0036 refers to “data received from third parties also can be downloaded and/or accessed from the user’s computer system **210** and/or the health monitoring device **100**.” However, the description of the user’s access to the user’s computer system **210** is devoid of any mention of security or authorization mechanisms.

Paragraph 0041 of Leven refers to “an operative wireless communications link can be detected automatically.” Leven further states that once “a link is detected and a connection is made, the present invention can transmit the collected health indicator data to a remotely located computer system.” Leven at ¶ 0041. However, there is no disclosure of “a recognition module ... configured to ... authorize access,” as claim 1 recites. In contrast, the detection and connection appear to be made without regard to the user’s identity or authorization. Although Leven further states that “data can be transmitted with a unique identifier corresponding to the user’s **215** identity,” (Leven at ¶ 0041), Applicant respectfully submits that such data is apparently used to tag the collected data with the user’s identity. This tagging allows “software configured to detect particular health indicators ... though comparison with reference models and/or user profiles” and also allows “software can send electronic alerts to the user’s doctor **225**,” as referred to in paragraph 0041 of Leven. Whatever the case, the unique identifier is not used to authorize either the connection or access to the health monitoring system **200**.

Paragraph 0044 begins with "... the invention disclosed herein can be used to transfer health monitor data concerning the user's **215** vital signs to an authorized third party **235**." The remainder of paragraph discusses how third parties can access such data. Clearly, these third parties do not include "a person implanted with the implantable medical device," as recited in claim 1. Moreover, any authorization or security referred to in ¶ 0044 is not to "authorize a person implanted with the implantable medical device access to the information access portal", as presently claimed, but to authorize third parties.

In sum, because Leven does not disclose (1) "an interface to an implantable medical device, the implanted medical device configured to sense and transmit patient health data to the patient management system and comprising a proximity recognition system" or (2) "a recognition module ... configured to ... authorize a person implanted with the implantable medical device access to the information access portal," Leven does not establish every element recited in claim 1. Therefore, a proper *prima facie* case of anticipation does not exist. Thus, Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of this claim.

Leven fails to establish every element of claim 33:

As discussed above with respect to claim 1, Applicant respectfully submits that Leven fails to disclose "an interface to an implantable medical device" and "a recognition module configured to ... authorize a person implanted with the implantable medical device access to the publicly accessible information access portal," as claim 33 presently recites.

Moreover, Applicant respectfully submits that Leven fails to disclose a "publicly accessible information access portal," as claim 33 recites. Leven refers to several computers, including a user computer system **210**, a doctor's computer system **220**, and a third party computer system **230**.

Leven's "user's computer system **210**" is not equivalent to Applicant's claimed "publicly accessible information access portal." Leven describes the "user's computer system **210**" in several places, each time conveying that the user's computer system **210** is personal to the user. For example, Leven states that "the present invention can include a conventional home computer system **210**" (Leven at ¶ 0038), that "the data can be processed, whether in the home of the user

215 on a local computer **210**...” (Leven at ¶ 0041), and refers to the user’s computer system **210** as a “user’s home computer **210**” (Leven at ¶ 0048).

In contrast, for claim interpretation, the PTO must apply to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. M.P.E.P. § 2111 citing *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Here, the term “publicly accessible” should be construed in contrast to “privately accessible.” A reasonable person would not consider Leven’s user’s home computer as being publicly available or accessible.

In light of this analysis, neither Leven’s “doctor’s computer system **220**” nor “third party computer system **230**” constitute a “publicly accessible information access portal.” As stated in Leven at paragraph 0036, a doctor’s computer system is for the use of “a medical service provider/health professional **225**” and as such, would not be publicly available. In addition, the third party computer system **230** is available to a third party **235**, examples include “an insurance agency, friends, relatives, or other authorized party.” Leven at ¶ 0036. A computer system at an insurance agency is not typically one available for public access. Additionally, computer systems of friends or relatives of the user/patient are arguably at least as private as the user’s computer system **210**. Furthermore, there is no disclosure of the friends or relatives using the user’s computer system **210** or vice versa. Hence, none of the computer systems referred to in Leven are equivalent to Applicant’s “publicly available information portal.”

In sum, because Leven does not disclose (1) “an interface to an implantable medical device” or (2) “a recognition module configured to ... authorize a person implanted with the implantable medical device access to the publicly accessible information access portal” or (3) a “publicly accessible information access portal,” Leven does not establish every element recited in claim 33. Therefore, a proper *prima facie* case of anticipation does not exist. Thus, Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of this claim.

Leven fails to establish every element of claim 34:

As discussed above with respect to claim 1, Applicant respectfully submits that Leven fails to disclose “detecting, at an electronic recognition module, a proximity recognition system in an implantable medical device implanted in the person,” because at least Leven fails to disclose an implantable medical device.

Moreover, as discussed above with respect to claim 1, Leven fails to disclose authorizing access to a person implanted with the implantable medical device. As such, Applicant respectfully submits that Leven also fails to disclose “granting the person access to a publicly accessible information access portal when the electronic recognition module positively identifies the person as one with a right to access the publicly accessible information access portal,” as claim 34 recites because granting the person access relies on the electronic recognition module found in the implantable medical device.

Moreover, as discussed above with respect to claim 33, Leven fails to disclose a “publicly accessible information access portal.” Thus, Applicant respectfully submits that Leven also fails to disclose “granting the person access to a publicly accessible information access portal...” as claim 34 recites.

In sum, because Leven does not disclose (1) “detecting, at an electronic recognition module, a proximity recognition system in an implantable medical device implanted in the person” or (2) “granting the person access to a publicly accessible information access portal when the electronic recognition module positively identifies the person as one with a right to access the publicly accessible information access portal” or (3) a “publicly accessible information access portal,” Leven does not establish every element recited in claim 34. Therefore, a proper *prima facie* case of anticipation does not exist. Thus, Applicant respectfully requests reconsideration and withdrawal of the § 102 rejection of this claim.

Concerning dependent claims 4, 13, 14, 16, 17, 26, 27, 30, 35-36, 44-46, 49, 53 and 54:

A claim in dependent form shall be construed to incorporate by reference all of the limitations of the claim to which it refers. 35 U.S.C. § 112 ¶4. Thus, if a reference does not anticipate or render obvious a base claim, the reference does not anticipate or render obvious a claim that depends on the base claim.

Applicant respectfully submits that the dependent claims 4, 13, 14, 16, 17, 26, 27, 30, 35-36, 44-46, 49, 53 and 54 depend directly or indirectly from independent claims 1, 33 or 34, respectively. As such, these dependent claims incorporate all the recitations of claims 1, 33 or 34. Accordingly, Applicant respectfully submits that these dependent claims are patentable for at least the reasons set forth above. Thus, Applicant respectfully requests withdrawal of the rejections of these claims. For brevity, Applicant reserves the right to present further remarks concerning the patentable distinctiveness of such dependent claims.

The Rejection of Claims Under § 103

3. Claim 53 were rejected under 35 U.S.C. 103(a) over Leven.
4. Claims 21, 22, 24, 25, 28, 29, 31 and 50 were rejected under 35 U.S.C. 103(a) over Leven in view of Seigel et al. (U.S. Publication No. 2001/0051879).
5. Claims 5-10 and 37-42 were rejected under 35 U.S.C. 103(a) over Leven in view of Walker et al. (U.S. Publication No. 2002/0013173).
6. Claims 19, 20, 47 and 48 were rejected under 35 U.S.C. 103(a) over Leven in view of Kalgren et al. (U.S. Publication No. 2002/0077562).
7. Claims 15, 18, 23, 51 and 52 were rejected under 35 U.S.C. 103(a) over Leven in view of Seigel et al. and in further view of Konrad (U.S. Patent No. 5,544,320).
8. Claim 60 was rejected under 35 U.S.C. 103(a) over Leven in view of Seigel et al. and in further view of Treyz et al. (U.S. Patent No. 6,526,335).
9. Claims 56-59 were rejected under 35 U.S.C. 103(a) over Leven in view of Iliff et al. (U.S. Patent No. 6,234,964).

A claim in dependent form shall be construed to incorporate by reference all of the limitations of the claim to which it refers. 35 U.S.C. § 112 ¶4. Thus, if a reference does not anticipate or render obvious a base claim, the reference does not anticipate or render obvious a claim that depends on the base claim.

Applicant respectfully submits that the dependent claims 5-10, 15, 18-25, 28, 29, 31, 37-42, 47, 48, 50-54, 56-59, and 60 depend directly or indirectly from independent claims 1, 33 or

34, respectively. As such, these dependent claims incorporate all the recitations of claims 1, 33 or 34. Accordingly, Applicant respectfully submits that these dependent claims are patentable for at least the reasons set forth above. Thus, Applicant respectfully requests withdrawal of the rejections of these claims. For brevity, Applicant reserves the right to present further remarks concerning the patentable distinctiveness of such dependent claims.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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